4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0109]

Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program." FDA is issuing this draft guidance to describe its policy regarding FDA's participation in the Voluntary Improvement Program (VIP). The VIP is a voluntary program facilitated through the Medical Device Innovation Consortium (MDIC) that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. The VIP builds on the framework piloted through FDA's 2018 Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program) and incorporates some of the successes and learnings from the pilot. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of

information in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF THE PUBLICATION OF THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-0109 for "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance*: Francisco Vicenty, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1534, Silver Spring, MD 20993-0002, 301-796-5577.

With regard to the proposed collection of information: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601, Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As part of Center for Devices and Radiological Health's (CDRH) 2016-2017 strategic priority to "Promote a Culture of Quality and Organizational Excellence," CDRH envisions a future where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Among its other regulatory activities, FDA evaluates manufacturers' compliance with

regulations governing the design and production of devices. Compliance with 21 CFR part 820, "Quality System Regulation," is a baseline requirement for medical device manufacturing firms.

In an effort to elevate and enhance manufacturing practices and behaviors through which quality and safety of medical devices can be improved, FDA has collaborated with various stakeholders, brought together through the MDIC public-private partnership, to develop the CfQ Pilot Program. FDA announced the voluntary CfQ Pilot Program in the *Federal Register* on December 28, 2017 (82 FR 61575).

As in the CfQ Pilot Program, the VIP oversees third-party appraisers who evaluate voluntary industry participants, and the VIP assesses the capability and performance of key business processes using a series of integrated best practices. Those practices are detailed in the Information Systems Audit and Control Association Capability Maturity Model Integration (CMMI) system. CMMI provides a roadmap that guides improvement towards disciplined and consistent processes for achieving key business objectives, including quality and performance. VIP uses a version of the CMMI appraisal appropriate for the medical device industry. This appraisal tool is referred to as the Medical Device Discovery Appraisal Program (MDDAP) model. The baseline appraisal using the MDDAP model covers 11 practices areas, including Estimating, Planning, and Configuration Management. As part of the VIP, and as in the CfQ Pilot Program, the VIP provides firms and FDA with information about the firm's capability and performance for activities covered in the third-party appraisal.

Details and results from the 2018 CfQ Pilot Program are outlined in MDIC's Case for Quality Pilot Report, available at https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality-pilot-activities.

This voluntary program is currently only available to eligible manufacturers of medical devices regulated by CDRH and whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (including under sections 510(k), 513, 515, and 520). The voluntary CfQ Pilot Program was implemented for devices regulated by

CDRH, and products regulated by the Center for Biologics Evaluation and Research (CBER) were not part of the CfQ Pilot Program. CBER is interested in hearing from manufacturers of device products regulated by CBER under sections 510(k), 513, 515, and 520 (21 U.S.C. 360(k), 360c, 360e, and 360j) about their interest in participating in such a program. CBER requests comments from stakeholders regarding the possible application of this program to CBER-regulated devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents and https://www.regulations.gov. Persons unable to download an electronic copy of "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 20039 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each

collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Voluntary Improvement Program

OMB Control Number 0910-NEW

The VIP is a voluntary program facilitated through the MDIC public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals and is intended to guide improvement to enhance the quality of devices. FDA is issuing the draft guidance entitled "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program" to describe its policy regarding FDA's participation in the VIP. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1,2]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Site manufacturer application	1	400	400	0.08 (5 minutes)	33
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	400	400	20	8,000
Total					8,065

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers in table have been rounded.

Based on device registration and listing data and informal feedback from stakeholders, we anticipate approximately 400 sites may participate in the VIP annually.

The estimated Average Burdens per Response are largely based on our experience with the voluntary CfQ Pilot Program and were determined in consultation with our subject matter experts who are familiar with this program.

Site Manufacturer Application

Third-party appraisers forward participating site manufacturers' applications to FDA. FDA confirms whether certain information in the application is consistent with FDA's existing records. This helps the third-party appraiser to determine the manufacturers' eligibility for participation in the VIP. We expect each application will take approximately 5 minutes to submit.

Aggregate Data Reporting

The third-party appraiser provides FDA with aggregated data across all participating manufacturer sites quarterly. The aggregate data is used to identify broad industry trends and patterns that FDA may consider in the benefit-risk considerations FDA routinely uses to inform planning, improve FDA resource allocations, improve review efficiency, and inform risk-based inspection planning. We expect that it will take approximately 8 hours to prepare and submit the aggregate data.

Summary of Site Appraisal

The third-party appraiser provides FDA with a summary of the appraisal result for each participating site. FDA intends to consider this information in the benefit-risk considerations FDA routinely uses to inform planning, improve FDA resource allocations, improve review efficiency, and inform risk-based inspection planning for firms that demonstrate capability and transparency around their manufacturing and product performance. We expect it will take approximately 20 hours to complete each summary.

The VIP and Certain Regulatory Submissions

FDA expects to gain insights into a participant's manufacturing processes and control capabilities intended to satisfy recommendations for certain PMA or HDE submissions (e.g., PMA/HDE 30-Day Change Notices, PMA/HDE Manufacturing Site Change Supplements, PMA/HDE Manufacturing Modules). Thus, participants in the VIP may be able to avail themselves of efficiencies that would prevent duplicate information and/or allow for least burdensome submissions to FDA. FDA plans to improve stakeholder opportunities to use modified templates for such submissions.

The draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073
7	Recalls	0910-0432
803	Medical Device Reporting	0910-0437
807, subparts A through D	Establishment Registration and Listing	0910-0625

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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